

#2/146 6/11/01

SHEET 1 OF 6

FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. NIH061.1CP1C2	APPLICATION NO. -Unknown- 09/756,411
INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (USE SEVERAL SHEETS IF NECESSARY)		APPLICANT Lori et al.	
		FILING DATE herewith	GROUP Art Unit 1623



## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)
**	1	4,708,818	11/24/87	Montagnier et al.			
**	2	5,026,687	06/25/91	Yarehian et al.			
**	3	5,110,600	05/05/92	Green			
**	4	5,300,059	04/05/94	Rubinstein et al.			
**	5	6,046,175	04/04/00	Lori et al.			
**	6	6,093,702	07/25/00	Malley et al.			
**	7	5,521,161	05/28/96	Malley et al.			
**	8	5,736,526	04/07/99	Malley et al.			
**	9	5,736,527	04/07/99	Malley et al.			

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
L**	10	EP 0 206 497	12/30/86	EPO	—	—		
**	11	WO 87/01284	03/12/87	WIPO	—	—		
JL	12	WO 92/08699	05/29/92	WIPO	—	—		
JL	13	WO 93/12782	07/08/93	WIPO	—	—		
JL	14	WO 93/23368	11/25/93	WIPO	—	—		
JL	15	WO 94/27590	12/08/94	WIPO	—	—		
JL	16	WO 95/17899	07/06/95	WIPO	—	—		

\*\* Duplicate of reference already of record on a PTO-892.

EXAMINER	J. E. Crane	DATE CONSIDERED	06/12/01
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EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
<i>JL</i>	17 Albert et al., <i>Experimental Cell Research</i> , 179: 417-428, 1988, ! "Deoxyadenosine Toxicity and Cell Cycle Arrest in Hydroxyurea-Resistant S49 T-Lymphoma Cells."
<i>JL</i>	18 Altman, L.K., <i>New York Times</i> , p. 38, Sunday, September 17, 1995, "Study Challenges AZT Role as the Chief Drug for H.I.V."
<i>JL</i>	19 Balzarini et al., <i>Molecular Pharmacology</i> , 32: 798-806, 1987, ! "2', 3'-Dideoxycytidine: Regulation of its Metabolism and Anti-retroviral Potency by Natural Pyrimidine Nucleosides and by Inhibitors of Pyrimidine Nucleotide Synthesis."
**	20 Barre-Sinoussi et al., <i>Science</i> , 220: 868-871, 1983, "Isolation of a T-Lymphotropic Retrovirus from a Patient at Risk for Acquired Immune Deficiency Syndrome (AIDS)."
<i>JL</i>	21 Biron et al., <i>Journal of Acquired Immune Deficiency Syndromes and Human Retrovirology</i> , 10(1): 36-40, 1995, ! "Anti-HIV Activity of the Combination of Didanosine and Hydroxyurea in HIV-1-Infected Individuals."
**	22 Bukrinsky et al., <i>Science</i> , 254: 233-237, 1991, "Quiescent T Lymphocytes as an Inducible Virus Reservoir in HIV-1 Infection."
**	23 Busso et al., <i>AIDS Res. Human Retroviruses</i> , 6(9): 1139-1146, 1990, "Cellular Pharmacology and Anti-HIV Activity of 2', 3'-Dideoxyguanosine."
**	24 Centers for Disease Control, <i>Morbidity Mortality Weekly Report</i> , 30(25): 305-308, July 3, 1981, "Kaposi's Sarcoma and <i>Pneumocystis</i> Pneumonia Among Homosexual Men."
**	25 Chew et al., <i>Nature</i> , 361: 650-654, 1993, "Use of Evolutionary Limitations of HIV-1 Multidrug Resistance to Optimize Therapy."
<i>JL</i>	26 Coffin, H., <i>Fundamental Virology 2nd Edition</i> , pp. 545-708, Raven Press, New York, 1991, ! "Retroviridae and Their Replication."
**	27 Fauci, <i>Science</i> , 239: 617-622, 1988, "The Human Immunodeficiency Virus: Infectivity and Mechanisms of Pathogenesis."
**	28 Fauci, <i>Science</i> , 262: 1011-1018, 1993, "Multifactoral Nature of Human Immunodeficiency Virus Disease: Implications for Therapy."
**	29 Fierino et al., <i>Antiviral Chemistry &amp; Chemotherapy</i> , 4(1): 55-63, 1993, "Prevention of Activation of HIV-1 by Antiviral Agents in OM-10.1 Cells."
<i>JL</i>	30 Fischl, <i>AIDS Clin. Rev.</i> , 94: 167-187, 1993, ! "Treatment of HIV Disease in 1993/1994."
	** Duplicate of reference already cited on a PTO-892. ! Month of publication data is unavailable for this reference.

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EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)		
**	31 Fox et al., <i>J. Infectious Diseases</i> , 164: 1051-1057, 1991, "Lymphoid Germinal Centers are Reservoirs of Human Immunodeficiency."		
Gre	32 Gao, <i>Aids Research and Human Viruses</i> , 10(1): Supp. 3, Abstract No. 355, 1994, ! "Mechanisms of the Enhanced Anti-HIV-1 Activities of 2', 3'-Dideoxynucleoside Analogs by Hydroxyurea."		
Gre	33 Gao et al., <i>Clinical Research</i> , 42(2): 280A, 1994, ! "Anti-HIV-1 Activity of Hydroxyurea in Combination with 2', 3'-Dideoxynucleosides."		
Gre	34 Gao et al., <i>Mol. Pharmacol.</i> , 46(4): 767-772, 1994, ! "Anti-Human Immunodeficiency Virus Type 1 Activity of Hydroxyurea in Combination with 2', 3'-Dideoxynucleosides."		
**	35 Gao et al., <i>Proc. Natl. Acad. Sci. USA</i> , 90: 8925-8928, October 1993, "Low levels of deoxynucleotides in peripheral blood lymphocytes: A strategy to inhibit human immunodeficiency virus type 1 replication."		
Gre	36 Goulaouic et al., <i>C.R. Acad. Sci. Paris</i> , 317: 430-436, 1994, ! "Potentiation of 2', 3'-Dideoxycytidine (ddC) by Hydroxyurea and Thymidine on the Moloney Murine Leukemia Virus (MoMLV) Early Replicative Steps."		
Gre	37 Goulaouic et al., <i>Virology</i> , 200: 87-97, 1994, ! "Exogenous Nucleosides Promote the Completion of MoMLV DNA Synthesis in GO-Arrested Balb c/3t3 Fibroblasts."		
Gre	38 Hao et al., <i>Molecular Pharmacology</i> , 34:431-435, 1988, ! "Factors Determining the Activity of 2', 3'-Dideoxynucleosides in Suppressing Human Immunodeficiency Virus In Vitro."		
**	39 Hirsch et al., <i>N. Engl. J. Medicine</i> , 328(23): 1686-1695, 1993, "Therapy for Human Immunodeficiency Virus Infection."		
Gre	40 Huber et al., <i>J. of Biological Chemistry</i> , 264(8): 4669-4678, 1989, ! "Human Immunodeficiency Virus I Reverse Transcriptase."		
Gre	41 Hubscher, H., <i>Experientia</i> , 39(1): 1-25, 1983, ! "DNA Polymerases in Prokaryotes and Eukaryotes: Mode of Action and Biological Implications."		
Gre	42 Ji et al., <i>Mol. Gen. Genet.</i> , 226: 257-264, 1991, ! "Analysis of Mutagenesis Induced by a Thermolabile T4 Phage Deoxycytidylate Hydroxymethylase Suggests Localized Deoxyribonucleotide Pool Imbalance."		
**	43 Karlsson et al., <i>Eur. J. Biochem</i> , 186: 689-694, 1989, "Hydroxyurea increases the phosphorylation of 3'-fluorothymidine and 3'-azidothymidine in CEM cells."		
Gre	44 Kati et al., <i>J. of Biological Chemistry</i> , 267(36): 25988-25997, 1992, ! "Mechanism and Fidelity of HIV Reverse Transcriptase."		

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<i>Jre</i>	45	Langreth, <i>The Wall Street Journal</i> , p. B12, November 21, 1995, "FDA Gives Approval to Glaxo, Sequis to Market Separate AIDS Therapies."	
**	46	Licastro-et-al., <i>Biochem-Biophys. Res. Comm.</i> , 132(3): 929-933, 1985, "Inhibition of Polymerases- $\alpha$ and - $\beta$ Completely Blocks DNA Repair Induced by UV Irradiation in Cultured Mouse Neuronal Cells."	
<i>Jre</i>	47	Lien, <i>Progress in Drug Research</i> , 31: 101-126, 1987, "Ribonucleotide reductase inhibitors as anticancer and antiviral agents."	
<i>Jre</i>	48	Lori et al., <i>Antiviral Res.</i> , Vol. 23, Supp. 1, page 63, 1994, ! "Hydroxyurea Inhibits HIV-1 Replication by Inducing Low dNTP Levels. A Cellular Enzyme as a Target to Inhibit HIV-1."	
<i>Jre</i>	49	Lori et al., <i>J. of Virol.</i> , 66(8): 5067-5074, 1992, ! "Viral DNA Carried by Human Immunodeficiency Virus Type 1 Virions."	
<i>Jre</i>	50	Lori et al., <i>International Conference on Aids</i> , 10(1): 8, Abstract No. 007b, 1994 ! "Hydroxyurea as a Novel Potent Inhibitor of HIV-1 Replication."	
**	51	Lori et al., <i>Science</i> , 266(5186): 801-805, 1994, "Hydroxyurea as an Inhibitor of Human Immunodeficiency Virus Type 1 Replication."	
<i>Jre</i>	52	Malley et al., <i>The Lancet</i> , 343(8908): 1292, 1994, ! "Suppression of HIV Production in Resting Lymphocytes by Combining Didanosine and Hydroxamate Compounds."	
<i>Jre</i>	53	Malley, <i>Proc. Nat. Acad. Sci. USA</i> , 91(23): 11017-11021, November 1994, "Synergistic Anti-Human Immunodeficiency Virus Type 1 Effect of Hydroxamate Compounds with 2', 3'-Dideoxyinosine in Infected Resting Human Lymphocytes."	
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<i>Jre</i>	55	Matsumoto et al., <i>The Journal of Immunology</i> , 131(6): 2762-2766, 1983, ! "Inhibition of RNA Synthesis by Deoxyadenosine Plus Deoxycoformycin in Resting Lymphocytes."	
<i>Jre</i>	56	McCune et al., <i>Cell</i> , 53: 55-67, 1988, ! "Endoproteolytic Cleavage of gp160 is Required for the Activation of Human Immunodeficiency Virus."	
<i>Jre</i>	57	Medina et al., <i>Antimicrobial Agents and Chemotherapy</i> , 36(5): 1127-1130, 1992, ! "Ganciclovir Antagonizes the Anti-Human-Immunodeficiency Virus Type I Activity of Zidovudine and Didanosine In Vitro."	
<i>JEC</i>	58	Meyerhans et al., <i>Journal of Virology</i> , 68(1): 535-540, 1994, ! "Restriction and Enhancement of Human Immunodeficiency Virus Type 1 Replication by Modulation of Intracellular Deoxynucleosides Triphosphate Pools."	

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<i>Re</i>	59	Meyerhans et al., <i>VIII International Conference on AIDS/III STD World Congress</i> , 2: A22-2118, July 1992, "The Intracellular Nucleotide Pool Effects HIV Replication."	
<i>Re</i>	60	New York Times, p. B19, November 24, 1995, "Study Puts Risk of H.I.V. in Young U.S. Men at 1 in 92."	
**	61	Pauwels et al., <i>J. Virological Methods</i> , 20: 309-321, 1988, "Rapid and Automated Tetrazolium-Based Colorimetric Assay for the Detection of Anti-HIV Compounds."	
<i>Re C</i> !	62	Pegoraro et al., <i>Experimental Cell Res.</i> , 68: 283-290, 1971, "Thymidine Kinase, Deoxycytidine Kinase and Deoxyctidylate Deaminase Activities in Phytohaemagglutinin Stimulated Human Lymphocytes."	
<i>Re</i> !	63	Perno et al., <i>J. of Exp. Medicine</i> , 168: 1111-1125, 1988, "Inhibition of Human Immunodeficiency Virus (HIV-1/HTLV-III Ba-L) Replication in Fresh and Cultured Human Peripheral Blood Monocytes/Macrophages by Azidothymidine and Related 2', 3'-Dideoxynucleosides."	
<i>Re</i> !	64	Popovic et al., <i>Science</i> , 224: 467-500, 1984, "Detection, Isolation, and Continuous Production of Cytopathic Retroviruses (HTLV-III) from Patients with AIDS and Pre-Aids."	
<i>Re</i> !	65	Robinson, W., <i>Fundamental Virology 2nd Edition</i> , pp. 989-1021, Raven Press, New York, 1991, "Hepadnaviridae and Their Replication."	
**	66	Root-Bernstein, R.S., <i>Genetic Engineering News</i> , pp. 4-6, September 1, 1992, "AIDS is Moore than HIV: Part I."	
**	67	Root-Bernstein, R.S., <i>Genetic Engineering News</i> , pp. 4-5, September 15, 1992, "AIDS is Moore than HIV: Part II."	
<i>Re</i> !	68	Safrin et al., <i>Journal of Medical Virology</i> , Supplement 1, pp. 146-149, 1993, "Potential for Combined Therapy with 348U87, a Ribonucleotide Reductase Inhibitor, and Acyclovir as Treatment for Acyclovir-Resistant Herpes Simplex Virus Infection."	
**	69	Schnittman et al., <i>Science</i> , 245: 305-308, 1989, "The Reservoir for HIV-1 in Human Peripheral Blood is a T Cell that Maintains Expression of CD4."	
**	70	Schoefs, <i>New York Times Magazine</i> , pp. 32-35, June 21, 1998, "The Berlin Patient."	
**	71	Sigma-Chemical Company, <i>catalog</i> , St. Louis, MO, pp. 321 and 341-342, 1992, "Biochemicals/Organic Compounds for Research and Diagnostic Reagents."	
<i>Re</i>	72	Simonelli et al., <i>European Aids Clinical Society, Book of Abstracts</i> , September 1995, "Hydroxyurea as an Antiretroviral Drug in HIV Infected Patients: Clinical, Immunological and Virological Evaluation."	

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EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)	
**	73 Snyder et al., <u>DNA Repair and Its Inhibition-Nucleic Acids-Symposium-Series-No. 13</u> , Collins et al., eds., Chapter 2, pp. 13-33, IRL Press, Oxford, England, 1984, "The Accumulation of DNA Breaks Due to Incision: Comparative Studies with Various Inhibitors."	
**	74 Snyder et al., <u>Mol. Pharmacol.</u> , 28(6): 574-580, 1985, "Effectsof Hydroxyurea and Thymidine Derivatives on the Uptake and Metabolism of Deoxycytidine and Arabinosylcytosine in Log Phase and Contact-Inhibited Human Fibroblasts."	
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<i>JRC</i>	76 T'Ang et al., <u>J. Med. Chem.</u> , 28: 1103-1106, 1985, ! "Optimization of the Schiff Bases of N-Hydroxy-N' aminoguanidine as Anticancer and Antiviral Agents."	
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<i>JRC</i>	78 Varmus et al., <u>RNA Tumor Viruses, Molecular Biology of Tumor Viruses 2nd Ed.</u> , Chapter 5, pp. 369-512, 1982, ! "Replication of Retroviruses."	
<i>JRC</i>	79 Vila et al., <u>Lancet</u> , 348(9021): 203-204, July 20, 1996, "1-year follow-up of the use of hydroxycarbamide and didanosine in HIV Infection."	
**	80 Vila et al., <u>The Lancet</u> , 350(9078): 635-636, August 30, 1997, "Absence of Viral Rebound After Treatment of HIV-Infected Patients with Didanosine [ddI] and Hydroxycarbamide [aka Hydroxyureal]."	
<i>JRC</i>	81 Villani, et al., "Pharmacokinetics of Hydroxyurea in Patients Infected with Human Immunodeficiency Virus Type I," <u>Journal of Clinical Pharmacology</u> , 36, 117-121 (1996)	
<i>JRC</i>	82 Wilson et al. <u>J. Clin. Invest.</u> , 64: 1475-1484, 1979, ! "Purinogenic Immunodeficiency Disease - Differential Effects of Deoxyadenosine and Deoxyguanosine on DNA Synthesis in Human T Lymphoblasts."	
**	83 Yarchoan et al., <u>N. Engl. J. Medicine</u> , 321(11): 726-738, 1989, "Clinical Pharmacology of 3'-Azido-2', 3'-dideoxythymidine (Zidovudine) and Related Dideoxynucleosides."	
**	84 Zack et al., <u>Cell</u> , 61: 213-222, 1990, "HIV-1 Entry into Quiescent Primary Lymphocytes: Molecular Analysis Reveals a Labile, Latent Viral Structure."	

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